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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ARAGON PHARMACEUTICALS, INC., JANSSEN BIOTECH, INC., and SLOAN-KETTERING INSTITUTE FOR CANCER RESEARCH, Plaintiffs, v. LUPIN LIMITED and LUPIN PHARMACEUTICALS, INC., Defendants.	Honorable Evelyn Padin, U.S.D.J. Civil Action No. 2:22-cv-02825 (EP)(LDW) **CONFERENCE DATE: October 18, 2022**
ARAGON PHARMACEUTICALS, INC., JANSSEN BIOTECH, INC., and SLOAN-KETTERING INSTITUTE FOR CANCER RESEARCH, Plaintiffs, v. ZYDUS WORLDWIDE DMCC, ZYDUS PHARMACEUTICALS (USA) INC., and ZYDUS LIFESCIENCES LIMITED,	Civil Action No. 2:22-CV-02964(EP)(LDW)

Defendants.	
ARAGON PHARMACEUTICALS, INC., JANSSEN BIOTECH, INC., THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, and SLOAN-KETTERING INSTITUTE FOR CANCER RESEARCH, Plaintiffs, v. SANDOZ INC., Defendant.	Civil Action No. 2:22-CV-03044(EP)(LDW)
ARAGON PHARMACEUTICALS, INC., JANSSEN BIOTECH, INC., THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, and SLOAN-KETTERING INSTITUTE FOR CANCER RESEARCH, Plaintiffs, v. EUGIA PHARMA SPECIALITIES LIMITED (A.K.A. EUGIA PHARMA SPECIALTIES LIMITED), AUROBINDO PHARMA USA, INC., and AUROMEDICS PHARMA LLC, Defendants.	Civil Action No. 2:22-cv-03186(EP)(LDW)
ARAGON PHARMACEUTICALS, INC., JANSSEN BIOTECH, INC., THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, and SLOAN-KETTERING INSTITUTE FOR CANCER RESEARCH, Plaintiffs, v. HETERO LABS LIMITED UNIT V, HETERO LABS LIMITED, and HETERO USA, INC., Defendants.	Civil Action No. 2:22-cv-03212-EP-LDW

JOINT DISCOVERY PLAN

Pursuant to the Court's Orders of September 1 and September 21, 2022 (docketed at D.I. 31 and D.I. 35 in Civil Action No. 2:22-cv-02825), counsel for plaintiffs Aragon Pharmaceuticals Inc., Janssen Biotech, Inc., The Regents of the University of California,[1] and Sloan-Kettering Institute for Cancer Research (collectively, "Plaintiffs"), and counsel for defendants Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively, "Lupin"); Zydus Worldwide DMCC, Zydus Pharmaceuticals (USA) Inc., and Zydus Lifesciences Limited (formerly known as Cadila Healthcare Limited) (collectively, "Zydus"); Sandoz Inc. ("Sandoz"); Eugia Pharma Specialities Limited (also known as Eugia Pharma Specialties Limited), Aurobindo Pharma USA, Inc., and AuroMedics Pharma LLC (collectively, "Eugia"); and Hetero Labs Limited Unit V and Hetero USA, Inc. (collectively, "Hetero"); (collectively, "Defendants"), respectfully submit this Joint Discovery Plan.

1. Set forth a factual description of the case. Include the causes of action and affirmative defenses asserted.

The actions subject to this Joint Discovery Plan are actions for patent infringement, as alleged in Plaintiffs' complaints. Plaintiffs' causes of action arise out of Defendants' respective submissions of Abbreviated New Drug Applications ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import a generic version of Erleada® (apalutamide) prior to the expiration of one or more of U.S. Patent Nos. 8,445,507; 8,802,689; 9,388,159; 9,481,663; 9,884,054; 9,987,261; 10,052,314; 10,702,508; and 10,849,888 (together, "Patents-in-Suit"), and involve the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, including 35 U.S.C. § 271(e)(2), the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355(j) (the "Hatch-Waxman Act"), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

Defendants have each filed Paragraph IV Certifications pursuant to 21

[1] The Regents of the University of California is a plaintiff in the following actions only: *Aragon Pharmaceuticals, Inc. et al. v. Sandoz Inc.*, 2:22-cv-03044-EP-LDW; *Aragon Pharmaceuticals, Inc. et al. v. Eugia Pharma Specialities Limited et al.*, 2:22-cv-03186-EP-LDW; and *Aragon Pharmaceuticals, Inc. et al. v. Hetero Labs Limited Unit V et al.*, 2:22-cv-03212-EP-LDW.

U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to one or more of the patents-in-suit. Defendants have asserted various affirmative defenses, including but not limited to noninfringement and invalidity of the claims of the patents-in-suit.

Parties to the below actions have submitted a status letter to the court, as listed in the table below, which provide an overview of issues in the cases.

Document	Action	D.I.
Plaintiffs' and Lupin's Joint Status Letter	2:22-cv-02825-EP-LDW	22
Plaintiffs' and Sandoz's Joint Status Letter	2:22-cv-03044-EP-LDW	19
Sandoz's Letter to the Court	2:22-cv-03044-EP-LDW	37
Plaintiffs' Response to Sandoz's Letter to the Court	2:22-cv-03044-EP-LDW	38
Plaintiffs' and Eugia's Joint Status Letter	2:22-cv-03186-EP-LDW	20
Plaintiffs' and Hetero's Joint Status Letter	2:22-cv-03212-EP-LDW	20

Plaintiffs assert the following Patents-in-Suit against each Defendant:

Eugia and Sandoz	the '689, '159, '261, '507, '663, '054, '314, '888, and '508 patents
Lupin and Zydus	the '663, '054, '314, '888, and '508 patents
Hetero	the '507, '663, '054, '314, '888, and '508 patents

2. Have settlement discussions taken place? **No**

3. The parties have not exchanged the information required by Fed. R. Civ. P. 26(a)(1). If not, state the reason therefor.

The parties will exchange Rule 26(a)(1) disclosures on November 2, 2022.

4. Describe any discovery conducted other than the above disclosures.

In each of the individual cases, the defendants produced their ANDAs.

5. Generally, dispositive Motions cannot be filed until the completion of discovery. Describe any Motions any party may seek to make prior to the completion of discovery. Include any jurisdictional Motions and Motions to Amend.

Sandoz will likely file a motion for judgment on the pleadings as to the infringement counts in Plaintiffs' First Amended Complaint for U.S. Patent Nos. 9,884,054; 9,987,261; 10,052,314; 10,702,508; and 10,849,888. *See* Sandoz's Letter to the Court dated September 19, 2022 (D.I. 37 in Case 2:22-cv-03044-EP-LDW).

One or more parties may seek to file discovery motions prior to the completion of discovery, to the extent the parties are unable to resolve any discovery issues without the Court's assistance. One or more parties may seek to file a motion to amend their pleadings. One or more parties may seek to file a motion to limit the number of asserted claims depending on the

number of claims asserted by Plaintiffs. Plaintiffs may seek to file a motion to limit the number of grounds and defenses asserted by Defendants.

6. The parties propose the following:

   a. Discovery is needed on the following subjects: **Discovery relating to the claims and defenses in the parties' pleadings, including infringement and validity of each of United States Patent Nos. 8,445,507; 8,802,689; 9,388,159; 9,481,663; 9,884,054; 9,987,261; 10,052,314; 10,702,508; and 10,849,888, as well as various related issues, claims, and affirmative defenses**.

   b. Should discovery be conducted in phases? If so, explain. **No, except that expert discovery should commence after the close of fact discovery, as set forth below**.

The parties request that the following cases be consolidated for discovery and all pretrial proceedings, including claim construction, and that the issue of consolidation for trial be revisited at a later date:

- Aragon Pharmaceuticals, Inc. et al. v. Lupin Limited et al., 2:22-cv-02825-EP-LDW
- Aragon Pharmaceuticals, Inc. et al. v. Zydus Worldwide DMCC et al., 2:22-cv-02964-EP-LDW
- Aragon Pharmaceuticals, Inc. et al. v. Sandoz Inc., 2:22-cv-03044-EP-LDW
- Aragon Pharmaceuticals, Inc. et al. v. Eugia Pharma Specialities Limited et al., 2:22-cv-03186-EP-LDW
- Aragon Pharmaceuticals, Inc. et al. v. Hetero Labs Limited Unit V et al., 2:22-cv-03212-EP-LDW

Defendants do not waive their right to a separate trial on issues unique to each of Sandoz, Hetero, Lupin, Eugia, and Zydus.

The following proposed discovery limits and timings are based on a consolidated case. For the purposes of this section:

- Aragon Pharmaceuticals, Inc., Janssen Biotech, Inc., The Regents of the University of California, and Sloan-Kettering Institute for Cancer Research collectively constitute the "Plaintiff Group."
- Lupin Limited and Lupin Pharmaceuticals, Inc. collectively constitute a "Defendant Group."
- Zydus Worldwide DMCC, Zydus Pharmaceuticals (USA) Inc., and Zydus Lifesciences Limited (formerly known as Cadila Healthcare Limited) collectively constitute a "Defendant Group."

- Sandoz Inc. constitutes a "Defendant Group."

- Eugia Pharma Specialities Limited (also known as Eugia Pharma Specialties Limited), Aurobindo Pharma USA, Inc., and AuroMedics Pharma LLC collectively constitute a "Defendant Group."

- Hetero Labs Limited Unit V and Hetero USA, Inc. collectively constitute a "Defendant Group."

c. **Number of Interrogatories:**

[**Plaintiffs' Position:** Plaintiff Group shall propound no more than **30** interrogatories on each Defendant Group. Defendant Groups collectively shall propound no more than **20** common interrogatories on Plaintiff Group, and each Defendant Group shall propound no more than **10** individual interrogatories on Plaintiff Group.]

[**Defendants' Position**: Plaintiff Group shall propound no more than **20** common interrogatories, to which each Defendant Group will separately respond, and Plaintiff Group may serve no more than **5** additional interrogatories on each Defendant Group. Defendant Groups collectively shall propound no more than **15** common interrogatories on Plaintiff Group, and each Defendant Group shall propound no more than **10** individual interrogatories on Plaintiff Group.]

The maximum number of interrogatories, which includes all discrete subparts, may be revised by agreement of the Parties or by order of the Court upon a showing of good cause.

d. **Number of Requests for Admission:** Except for evidentiary purposes, such as Requests for Admission for authentication purposes only,

[**Plaintiffs' position**: Plaintiff Group shall propound no more than **30** requests for admission on each Defendant Group. Defendant Groups collectively shall propound no more than **20** common requests for admission on Plaintiff Group, and each Defendant Group shall propound no more than **10** individual requests for admission on Plaintiff Group.]

[**Defendants' position**: Plaintiff Group shall propound no more than **40** common Requests for Admission, to which each Defendant Group will separately respond, and Plaintiff Group may jointly serve no more than **10** additional Requests for Admission. Defendant Groups collectively shall propound no more than **40** common requests for admission on Plaintiff Group, and each Defendant Group shall propound no more than **10** individual requests for admission on Plaintiff Group.]

The maximum number of Requests for Admission may be revised by agreement of the Parties or by order of the Court upon a showing of good cause.

e. **Number of Depositions to be taken by each side:** Plaintiff Group may jointly take a maximum of 21 hours of fact depositions of Defendant Group witnesses per Defendant

Group. Defendants may jointly take a maximum of 105 hours of fact depositions of Plaintiff Group witnesses. Any depositions pursuant to Fed. R. Civ. P. 30(b)(6) are subject to the fact deposition time limitations set forth in this paragraph.

[Plaintiffs' position: No witness will be produced more than once for deposition, unless the witness is produced in both an individual and a 30(b)(6) capacity.]

[**Defendants' position**: No witness will be produced more than once for deposition.]

No witness will be produced for more than 7 hours absent agreement of the parties or for good cause shown. Any witness who appears on a trial witness list (or as a declarant in any motion practice) may be deposed notwithstanding the foregoing limit. Depositions of third parties and experts shall not count against the foregoing limits. The total hours may be revised by agreement of the Parties or by Order of the Court upon a showing of good cause.

The Parties agree to cooperate to avoid unnecessary duplication of deposition testimony.

For purposes of fact depositions conducted in a language other than English, one (1) hour of deposition conducted with the use of a translator will be deemed to count as 0.5 hours.

The parties agree to work in good faith to accommodate requests that any deposition may take place on Zoom or other videoconference platform.

f. Set forth any special discovery mechanism or procedure requested, including data preservation orders or protective orders:

The parties will submit a proposed Stipulated Confidentiality Order pursuant to L. Pat. R. 2.2 on **November 1, 2022**.

g. Amending pleadings or joining parties without leave of the Court no later than **January 3, 2023**.

Contentions

h. Plaintiffs disclose asserted claims pursuant to L. Pat. R. 3.6(b) on **October 25, 2022**.

i. Defendants' Invalidity and Non-Infringement Contentions and accompanying documents pursuant to L. Pat. R. 3.6(c)-(f) on **December 21, 2022**.

j. Plaintiffs' Infringement Contentions and accompanying documents pursuant to L. Pat. R. 3.6(g)-(h) on **March 23, 2023**.

k. Plaintiffs' response to Invalidity Contentions pursuant to L. Pat. R. 3.6(i) on **March 23, 2023**.

Claim Construction

l. Parties exchange list of claim terms in need of construction on **March 30, 2023**.

m. Parties exchange preliminary proposed constructions and identify intrinsic and extrinsic evidence on **April 13, 2023**.

n. Parties exchange intrinsic and extrinsic evidence to oppose proposed constructions on **April 27, 2023**.

o. Joint Claim Construction and Prehearing Statement submitted on **May 11, 2023**.

p. Deadline to complete fact discovery relating to claim construction on **June 8, 2023**.

q. Opening Claim Construction Briefs submitted on **June 29, 2023**.

r. Parties Complete Expert Discovery Relating to Opening Markman Submissions on **July 27, 2023**.

s. Responsive Claim Construction Briefs on **August 17, 2023.**

t. Parties confer to propose a schedule for the claim construction hearing by **August 31 2023**.

u. Claim construction hearing to be held on **September __, 2023** or **at the Court's convenience**.

Fact Discovery

v. Substantial Completion of Document Production by [Plaintiffs' position: **November 30, 2023**] [Defendants' position: **September 29, 2023**].

w. Fact discovery to be completed by [Plaintiffs' position: **May 23, 2024**] [Defendants' position: **March 29, 2024**].

Experts

x. Opening expert reports on issue for which party bears the burden due on [Plaintiffs' position: **June 27, 2024**] [Defendants' position: **April 30, 2024**].

y. Rebuttal expert reports, including opening reports on objective indicia, due on [Plaintiffs' position: **August 8, 2024**] [Defendants' position: **June 27, 2024**].

z. Reply expert reports on objective indicia due on [Plaintiffs' position: **September 5, 2024**] [Defendants' position: **July 18, 2024**].

aa. Expert discovery to be completed by [Plaintiffs' position: **October 10, 2024**] [Defendants' position: **September 12, 2024**].

Pretrial and Trial

bb. Opening summary judgment and Daubert motions due no later than [Plaintiffs' position: **November 7, 2024**] [Defendants' position: **October 10, 2024**].

cc. Response to summary judgment and Daubert motions due no later than [Plaintiffs' position: **December 5, 2024**] [Defendants' position: **October 31, 2024**].

dd. Reply to summary judgment and Daubert motions due no later than [Plaintiffs' position: **December 19, 2024**] [Defendants' position: **November 14, 2024**].

ee. Submission of pretrial order is **subject to the date of the pretrial conference.**

ff. A pretrial conference may take place on **T.B.D.**

gg. Trial by jury or non-jury Trial? **Non-jury trial**.

hh. Trial date: **February 10, 2025 or at the Court's convenience**.

ii. End of Regulatory Approval Stay: **August 14, 2025**.

7. Do you anticipate any discovery problem(s)? **No.**

8. Do you anticipate any special discovery needs (i.e., videotape/telephone depositions, problems with out-of-state witnesses or documents, etc.)? **Yes.**

This case may include seeking discovery from foreign-based entities and U.S.-based entities with foreign operations, potentially including witnesses that reside outside the U.S. The parties agree to meet and confer regarding a mutually acceptable agreement to produce foreign witnesses for deposition, including conducting depositions remotely where appropriate. Discovery may include seeking physical materials such as pharmaceutical materials that are kept in foreign countries. In addition, the parties anticipate taking discovery from third party inventors of the patents-in-suit and third party inventors and/or authors of prior art.

9. State whether this case is appropriate for voluntary arbitration (pursuant to L. Civ. R. 201.1 or otherwise), mediation (pursuant to L. Civ. R. 301.1 or otherwise), appointment of a special master or other special procedure. If not, explain why and state whether any such procedure may be appropriate at a later time (i.e., after exchange of pretrial disclosures, after completion of depositions, after disposition of dispositive motions, etc.).

At this time, the parties do not believe that this case is appropriate for voluntary arbitration or mediation, or requires a special or other special procedure at present, but believe that the foregoing may be appropriate at a later time.

10. Is this case appropriate for bifurcation? **No.**

11. We **do not** consent to the trial being conducted by a Magistrate Judge.

12. Additional Discovery Plan Topics Set Forth in L. Pat. R. 2.1(a)

a. (1) Proposed modification of the obligations or deadlines set forth in these Local Patent Rules to ensure that they are suitable for the circumstances of the particular case (see L. Pat. R. 1.3);

The Parties have proposed modifications to the deadlines above.

b. (2) The scope and timing of any claim construction discovery including disclosure of and discovery from any expert witness permitted by the court;

The parties have addressed this issue in the deadlines above.

c. (3) The format of the Claim Construction Hearing, including whether the Court will hear live testimony, the order of presentation, and the estimated length of the hearing;

The parties will submit this information in the Joint Claim Construction and Prehearing Statement on the date set forth above.

d. (4) How the parties intend to educate the Court on the patent(s) at issue;

The parties intend to educate the Court on the patents at issue through at least submissions to the Court in connection with the *Markman* proceedings, which may include technology tutorial(s).

e. (5) The need for any discovery confidentiality order and a schedule for presenting certification(s) required by L. Civ. R. 5.3(b)(2).

The parties will submit a proposed discovery confidentiality order at the date set forth above.

f. (6) The availability and timing of production of invention records (including inventor laboratory notebooks and analytical test results);

Plaintiffs shall produce invention records by March 23, 2023.

g. The availability and timing of production of ANDA product research and development documents;

[Plaintiffs' position: Defendants' shall produce ANDA product research and development documents by January 23, 2023. Defendants will supplement their disclosures as required by the Federal Rules.]

[Defendants' position: Defendants' investigation regarding the availability and timing of production of ANDA product research and development documents is ongoing.]

h. The availability and timing of production of ANDA product samples;

[Plaintiffs' proposal: Defendants' shall produce ANDA product samples by January 23, 2023.]

[Defendants' proposal: Defendants disagree with Plaintiffs' proposal to set a single court-ordered date for the production of ANDA product samples for all Defendants. Each Defendants' situation differs with respect to the availability of unexpired samples and access to the samples. Defendants' investigation of the availability of ANDA product samples is ongoing. To the extent production of ANDA product samples is relevant to any party's claims or defenses and proportional to the needs of the case, and such materials are timely requested, Defendants agree to meet and confer in good faith regarding the production of any non-privileged unexpired ANDA product samples that are within the possession, custody, and control of Defendants.]

i. The date of conception and the date of reduction to practice for each patent asserted in the action, if applicable;

Plaintiffs will provide the information required by the Local Patent Rules with their contentions.

j. Each inventor's availability for deposition in the matter;

Plaintiffs will identify all of the named inventors over which Plaintiffs have control for deposition in their FED. R. CIV. P. 26(a)(1) disclosures.

k. Availability of foreign witnesses for deposition and foreign documents;

The parties will meet and confer regarding the availability of foreign witnesses for deposition and foreign documents and work in good faith to resolve any disputes relating thereto.

l. Whether there is a 30-month stay and if so, when it ends;

There is a stay of regulatory approval pursuant to 21 U.S.C. § 355(j)(5)(F)(ii) that expires on August 14, 2025.

m. A date for substantial completion of document production and a method for determining compliance;

A date for substantial completion of document production is set forth above. The parties will confer in good faith to ensure compliance with this.

n. Any other issues or matters that a party believes are time sensitive.

None.

Respectfully Submitted,

Dated: October 14, 2022

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